J. Subpart J, Part 422

Subpart J of part 422 has been reserved for future use.

K. Contracts with M+C Organizations (Subpart K)

Subpart K sets forth provisions relating to the contracts that are entered into by M+C organizations, including a description of terms that must be included in the contract, the duration of contracts, provisions regarding the nonrenewal or termination of a contract, and minimum enrollment, reporting, and prompt payment requirements.

1. Definitions (§422.500)

Comment: As discussed above in section II.F.2, we received comments suggesting that we impose requirements on providers to cooperate with M+C organizations in their collection of encounter data to be used in implementing risk adjustment.

Response: As discussed in section II.F.2, in response to this comment, we have taken several steps to facilitate the cooperation of providers in supplying valid data that can be used by M+C organizations to comply with encounter data requirements. In the case of contracting providers, we have specified under §422.257 that M+C organizations may include in their provider contracts provisions requiring submission of valid data. Therefore, an M+C organization could provide in its contract that it will not make payment if claims do not meet the standards specified. In the case of noncontracting providers, however,

§422.520 requires M+C organizations to pay 95 percent of "clean claims" within 30 days, or pay interest on the amount. Also, based on the existing definition of "clean claims," an M+C organization could not withhold payment based on a failure to submit a claim in the form required for use in complying with encounter data requirements. As noted in section II.F.2, we are revising the definition of "clean claim" in §422.500 to require that clean claims include the substantiating documentation needed to meet the requirements for encounter data submission, and meet the original Medicare "clean claim" requirements. This change will, in effect, also require noncontracting providers submitting claims to an M+C organization to provide the organization with the information it needs to be able to use the claim in encounter data submissions, by exempting claims that do not meet these requirements from application of the 30-day "prompt payment" standards articulated at §422.520. M+C organizations will therefore be able to withhold payment longer than the 30-day prompt payment standard in cases where noncontracting providers submit claims that do not contain substantiating documentation necessary for encounter data submissions or have other deficiencies (for example, inadequate coding). We believe that this clarification of the clean claim definition at §422.500 is consistent with section 1957(f)(1) of the Act, which incorporates the Medicare fee-for-service prompt payment provisions in sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act, and simply fleshes out the concept in the existing definition that a claim is not clean if it lacks "any required substantiating documentation." Providers should note that submission of claims with complete and accurate encounter data is ultimately in their best interest, since M+C organizations must submit complete and accurate encounter data in order to get the full payment to which they are entitled under the risk adjustment system. While HCFA does not regulate payments to providers by M+C organizations, we believe that M+C organizations should share appropriately with providers any gains under the risk adjustment system.

2. National Contracting

The BBA does not specifically define or directly address the issue of national contracting. It facilitated such contracting, however, when it provided in section 1857(a) of the Act that an M+C contract "may cover more than 1 Medicare+Choice plan," and, in section 1851(h)(3) of the Act, provided that marketing material need only be approved once to the extent it is consistent from area to area. While we are interested in national contracting, we similarly have not expressly provided for it in the regulations. One national contracting approach we would be willing to consider would permit an M+C applicant to request that we enter into a national contract with the applicant if the applicant holds license as a risk-bearing entity in each

State where it intends to operate. The applicant would have the option of adopting a single M+C plan across the country, with one service area and a national ACR proposal, or offering different M+C plans in different areas under the same national contract.

While we have not at this time entered into a national contract with any M+C organization, HCFA has entered into national "agreements" with national chain organizations that hold M+C contracts. These arrangements apply to those chain organizations that enter into separate contracts in multiple States. These agreements allow a chain organization to establish a uniform policy across all of its States as to marketing, quality assurance, utilization review, claims processing, etc. HCFA pre-approves these national policy procedures. We continue to contract separately with individual, albeit related, M+C organizations affiliated through common ownership or control. We likewise continue to monitor operational activities for each organization in each State, but, having approved national policy, the need for review at the State and local level is reduced.

Nine commenters addressed national contracting for M+C organizations. While most of the public comments favored extending the option of national contracting to M+C organizations and applicant organizations, commenters generally linked their support for the concept to a request that we provide additional information on the specifics of any national contracting policy.

Comment: While several commenters that supported national contracting raised individual concerns, (in most instances related to the need for HCFA to provide additional information), one commenter raised concerns that national contracting would undermine our ability to adequately monitor the performance of M+C organizations. Another commenter raised concerns that national contracting would provide M+C organizations the ability to bypass existing limits pertaining to the provision of cross-state and national radiology services.

Response: We continue to believe that national contracting has potential advantages for Medicare beneficiaries, M+C organizations, and HCFA. Indeed, we have already observed the benefits of allowing M+C organizations that operate in many markets throughout the county to establish uniform operational functions in the areas of marketing, quality assurance and claims processing. However, some issues pertaining to national contracting, (for example, monitoring and oversight, enforcement actions, etc.), require additional study. While HCFA continues to explore these issues, we are not able to provide detailed guidance. At such time as additional guidance is developed, we anticipate notifying the public through an operational policy letter.

3. Compliance Plan (§422.501(b)(3)(vi))

As a condition for entering into an M+C contract with HCFA, applicant organizations must demonstrate that they have certain administrative and management arrangements in place. There are six specific administration and management requirements at §422.501(b)(3). One of these requirements is that M+C organizations have in place a compliance plan for meeting all applicable Federal and State standards. The regulations list the required elements of the compliance plan, which generally follow the standards applied under the U.S. Sentencing Commission's Federal Sentencing Guidelines in determining whether the existence of a compliance plan should mitigate penalties. We received nine public comments on the M+C compliance plan requirement.

Comment: Although some commenters agreed with the spirit of the compliance plan requirement, most objected to its mandatory nature, especially in light of OIG guidance on compliance plans for M+C organizations.

Response: We believe that the unique financial incentives and health care delivery systems of M+C organizations justify the compliance plan requirement. Medicare beneficiaries who enroll in plans are essentially "locked in" to that plan's benefit structure and provider network and may not obtain services under original Medicare. M+C organizations are responsible for a significantly broader range of program activities than original

Medicare providers, including marketing, enrollment, appeals and grievances, utilization management, and claims payment. Each of these activities presents the potential for noncompliance that could directly and adversely affect a beneficiary's rights under the Medicare program. For example, an M+C organization's failure to report enrollment data properly to HCFA may result in incorrect payments to that organization.

While HCFA and the OIG conduct ongoing M+C program monitoring and enforcement activities, the number and variety of M+C operational requirements presents a significant regulatory challenge to both of these agencies. As a result, we believe that the additional level of scrutiny imposed by a compliance plan is a reasonable requirement.

While the OIG stated in its November 1999 guidance that the document was intended only to provide assistance for M+C organizations, the OIG did note that it "believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, and ensuring the provision of high-quality cost-effective care." The OIG also stated that a compliance plan is a tool for an M+C organization "to ensure that it is not submitting false or inaccurate information to the Government or providing substandard care to Medicare beneficiaries..." We agree with the OIG's judgement with respect to the utility of the compliance plan tool and have adopted this requirement to protect the integrity of the M+C program.

Comment: Several commenters asked when M+C organizations are responsible for meeting the compliance plan requirements stated at §422.501(b)(3)(vi), and noted that no detailed guidance on compliance has been issued by HCFA in connection with the interim final rule.

Response: The requirements in §422.501(b)(3)(vi), as revised in this final rule, are in effect and must be met by M+C applicants and M+C organizations. Pending any further guidance, M+C organizations are free to reasonably interpret the provisions in §422.501(b)(3)(vi), and should be prepared to demonstrate, upon request, how the organization meets each compliance plan element, as specified at §422.501(b)(3)(vi), et seq.

Comment: Many commenters addressed the requirement at §422.501(b)(3)(vi)(H) that M+C organizations develop "an adhered-to process for reporting to HCFA and/or the OIG credible information of violations of law by the M+C organization, plan, subcontractor, or enrollee for determination as to whether criminal, civil, or administrative action may be appropriate." Commenters generally stated that this requirement was too vague, and should be more clearly defined to enable organizations to demonstrate compliance to HCFA. Several commenters requested that we specify what "credible information" means within the context of requiring M+C organizations to submit information to HCFA and/or the OIG. Commenters also requested that we specify: (1) exactly what information must be self-reported; (2) to which agency; and (3) pursuant to violations of which laws. Commenters also noted that while paragraphs (A) through (G) correspond to provisions found in the Federal Sentencing Guidelines, paragraph (H) appears to be an M+C requirement only. These commenters believe that it is unfair to subject M+C organizations to a self-reporting requirement that does not apply to other sectors of the health care industry.

Response: Commenters correctly point out that the first seven elements of the mandated compliance plan guidance at §422.501(b)(3)(vi) et seq. reflect the areas identified in the U.S. Federal Sentencing Guidelines. We previously added the eighth element in an attempt to ensure an enhanced level of program safeguard through self-reporting. We recognize, however, that it is arguably unfair to impose a self-reporting requirement on M+C organizations but not on other types of health care providers and suppliers participating in the Medicare program, and we have eliminated any requirement of self-reporting.

Nevertheless, we believe that the existence of voluntary self-reporting procedures of potential misconduct is an appropriate part of an M+C organization’s compliance program.

While this rule does not make any type of self-reporting mandatory, M+C organizations may wish to consider the following suggestions, as a matter of voluntary good business practice. These suggestions are not mandatory. Where the M+C organization discovers evidence of misconduct related to payment or delivery of health care items or services under the M+C contract, the M+C organization may conduct a timely, reasonable inquiry into the misconduct. After the reasonable inquiry, if the organization has determined that the misconduct resulted in an overpayment, the M+C organization is encouraged voluntarily to report the overpayment to HCFA. If the M+C organization has determined that the misconduct may violate the statutes of direct concern to the HHS Office of Inspector General, it is encouraged voluntarily to report the existence of the misconduct to that office. Finally, the M+C organization is encouraged voluntarily to initiate and implement appropriate corrective actions to ensure the problem does not recur.

While we are withdrawing all requirements for self-reporting in this rule, we believe that the required reporting of overpayments is an effective tool for promoting Medicare program integrity generally. Accordingly, HCFA intends to develop policies through separate notice and comment rulemaking in cooperation with the HHS Office of Inspector General that would require all Medicare providers, suppliers and contractors to report overpayments to HCFA.

Comment: Some commenters considered the M+C compliance plan requirements at §422.501(b)(3)(vi) to be overly prescriptive, and asserted that they would result in M+C organizations being forced to "reinvent the wheel," even though they may have existing compliance structures in place that meet the intent of the regulations. Many of these same commenters questioned our authority to prescribe these requirements in the M+C final rules.

Response: It is not our intent through these rules to require M+C organizations with effective compliance plans in place to make major changes. We believe that the requirements in §422.501(a)(3)(vi) based on the Federal Sentencing Guidelines are sufficiently broad and general in nature that an effective compliance plan currently in place should satisfy M+C requirements. However, we do want some assurances that M+C organizations will have procedures in place to ensure compliance with Federal laws and requirements. We believe that our compliance plan requirements include the basic framework required for organizations to prevent and detect activities that will render the organization out of compliance. Moreover, the elements of the Federal Sentencing Guidelines from which these requirements are drawn are present in other guidances issued by the OIG over the last several years and should be familiar to most M+C compliance officials.

M+C organizations and contract applicants have broad discretion under §422.501(b)(3)(vi) to design their compliance plan structure to meet the unique aspects of each organization. We recognize that there is no one best way for an organization to take steps to ensure that it is operating in compliance with all applicable regulations and requirements. Thus, we intend to work with M+C organizations and contract applicants to apply a flexible standard in reviewing M+C compliance plans, while still ensuring that these compliance plans serve their intended purpose: to detect and prevent compliance problems, in addition to identifying aspects of the organization that may be vulnerable to such problems.

We believe that one way for us to determine if an organization's corporate compliance plan is effective is to evaluate and audit the performance of the organization according to the M+C requirements articulated in the M+C contract and regulations. Since we have an established monitoring process for M+C organizations, we believe that the infrastructure is already established that may assist HCFA in its efforts to assess the effectiveness of organizations' compliance plans based in part on the results of our monitoring efforts.

4. Access to Facilities and Records (§422.502(e))

Under §422.502(e) of the regulations, an M+C organization must agree to allow access to HHS or the Comptroller General to evaluate the quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract; the facilities of the M+C organization; and the enrollment and disenrollment records for the current contract period, and 6 prior contract years. We received two comments regarding access to M+C organization records.

Comment: A commenter asked what an M+C organization's obligations are in relation to information concerning nonplan providers, with whom an M+C organization has no contract. The commenter questioned how M+C organizations could be expected to provide access to governmental entities for nonplan provider records in order to meet the requirements of §422.502(e).

Response: We recognize that HHS, the Comptroller General or their designees can require only M+C organizations and their subcontractors to make available their facilities and records. If an M+C organization does not have a contract or other suitable written arrangement with a provider, it cannot compel the provider to provide the same access that an M+C organization or its subcontractors must provide under the terms of their M+C contract with HCFA. In order for HHS or the Comptroller General to gain access to the facilities and records of noncontracting providers, these agencies would be required to resort to other available legal remedies, such as subpoenas.

We would add, however, that as a general principle, if Federal funds are going to a provider of Medicare or Medicaid services, appropriate Federal officials have a right to review that provider's facility or books as a condition of receipt of those Federal funds.

Comment: A commenter suggested that the 6-year time period for which data must be retained under the regulations should be tied to the end of the year in question, and not the date of the completion of the audit, as provided in §422.502(e)(4).

Response: The 6-year period specified for retention of records was established in reliance on the 6-year "statute of limitations" that generally governs the initiation of a civil action by the Government, either under the False Claims Act (FCA) or the Civil Monetary Penalties Law (CMPL). A statute of limitations specifies the time period during which the Government may initiate an action. Generally, a statute of limitations begins to run on the date that an audit was completed. For this reason, we are requesting that books and records be kept for at least 6 years from either the end of a contract or the completion of an audit, whichever is later.

For purposes of clarity, we also point out that the 6-year record retention requirement requires M+C organizations to keep a specific year’s records for 6 years, after which the organization is free to dispose of any records they deem appropriate. This is to clarify one misconception that M+C organizations must maintain 6 years of records for an additional 6-year period. We instead envision the obligation for M+C organizations to retain records to expire on a rolling basis, with M+C organizations having the right to discard each year the records from more than 6 years earlier. For example, in 2000, M+C organizations could discard records from 1993 or earlier. In 2001, M+C organizations could discard records from 1994, etc. Under this system of record retention, if the Government has not audited or determined any wrongdoing within a 6-year period following the year when records were developed, the Government would be otherwise precluded under law from taking any action against an M+C organization.

5. Disclosure of Information (§422.502(f)(2)(v))

Pursuant to authority at section 1851(d) of the Act, §422.502(f)(2) describes the information that M+C organizations must submit to HCFA. We specify that this information is necessary for us to fulfill our responsibilities in evaluating and administering the program. Our dissemination of some of this information to current and prospective Medicare beneficiaries enables them to exercise informed choice in obtaining Medicare services. We received one comment on this section of the interim final rule.

Comment: One individual commented on the requirement in §422.502(f)(2)(v) that M+C organizations submit to us information about beneficiary appeals and their disposition. The commenter recommended that we amend this section of the regulations to include the additional requirement that M+C organizations disclose to HCFA information regarding beneficiary grievances and their disposition.

Response: Consistent with section 1852(c)(2)(c) of the Act, §422.111(c)(3) of the regulations distinguishes between information that an M+C organization must provide to a Medicare enrollee annually, and information that the M+C organization must disclose to any M+C eligible individual upon request. The requirement states that M+C organizations must disclose to M+C eligible individuals, upon request, the aggregate number of disputes, and their disposition, including both grievances and appeals. Thus, Medicare beneficiaries have access to information on M+C organization grievances.

Also, pursuant to both sections 1851(d)(3) and 1852(c)(2)(C) of the Act, §422.502(f) requires that M+C organizations disclose to us the appeal data that they are required to disclose upon request to beneficiaries. We believe that this is necessary so that we can begin to capture important baseline data on the appeals process. Our contractor (the Center for Health Disputes Resolution) is responsible for making reconsideration decisions when an enrollee files an appeal, and these decisions are appealed to HHS administrative law judges and the Departmental Appeals Board. In addition, HCFA enforces decisions made by these entities, which necessarily involve the critical question of whether services will be covered by the M+C organization.

While the regulations provide for beneficiary access to information on an M+C organization's grievance process, we do not at this time believe that it is necessary for HCFA to collect this information for administrative purposes. We would advise M+C organizations, however, that while we are not requiring that M+C organizations disclose grievance data to us at this time, we intend to propose additional requirements pertaining to M+C grievances, including quality of care grievances, in a notice of proposed rulemaking to be published later this year. Thus, we anticipate that M+C organizations may be required to report grievance data in the future.

6. Beneficiary Financial Protection (§422.502(g))

In the interim final rule, we addressed enrollee financial protection provisions at §422.502(g). These provisions are designed to protect enrollees from incurring liability for payment of any fee for which M+C organizations are legally obligated. Section 422.502(g) incorporates enrollee financial protections that were in place before the BBA in §417.122(a)(1), which applies to all section 1876 contractors under §417.407(f).

Section 422.502(g)(1) is intended to protect enrollees from being held financially responsible for fees for which the M+C organization is legally liable; §422.502(g)(2) addresses M+C organizations' obligation to provide for continued coverage of health care benefits, and §422.502(g)(3) sets forth the mechanisms M+C organizations can employ to provide the required enrollee protections. We received three comments regarding §422.502(g).

Comment: A commenter suggested that we provide appropriate "hold harmless" language for inclusion in M+C organizations' contracts because different States have different requirements regarding hold harmless language. (By "hold harmless" language, the commenter is referring to language included in an M+C organization's contract with a provider that protects enrollees from being charged for services, (other than pursuant to M+C plan provisions that allow for cost-sharing), furnished by the provider, even if the provider has not received payment from the M+C organization for the services.)

Response: Implicit in the commenter's request is recognition that many States have adopted hold harmless contract language requirements for managed care organizations operating within a given State. We generally recommend that M+C organizations adopt the National Association of Insurance Commissioners' (NAIC) model hold harmless language. However, given the wide variety of individual State requirements loosely categorized under member or enrollee protections, we do not believe that it is prudent to <u>require</u> M+C organizations to adopt the NAIC model language, because that requirement may well place some M+C organizations at odds with State provisions. The NAIC-approved language is available through most State insurance commissioners' offices, or by contacting the NAIC directly.

<u>Comment</u>: One commenter recommended that we strengthen the beneficiary protection provisions in subpart K by explicitly prohibiting providers from bringing "collection actions" against M+C enrollees, as a means of preventing providers from billing beneficiaries enrolled in M+C plans for fees that are the legal obligation of the M+C organization. The commenter also suggested that we define the word "fees" for purposes of this section of the regulations.

<u>Response</u>: Section 422.502(g)(1) is designed to ensure that beneficiaries are not held liable for fees for which the M+C organization is legally responsible. As discussed above, under §422.502(g)(1)(i), contracts with M+C plan providers must contain language that prohibits these providers from holding beneficiary enrollees liable for payment of fees that are the obligation of the M+C organization. (This language is commonly referred to as "hold harmless" language.) Under §422.502(g)(1)(ii), M+C organizations are responsible for indemnifying enrollees for

payment of any fees that are the legal obligation of the M+C organization to pay when services are furnished by providers that do not have a contract or other acceptable written arrangement with the M+C organization. We believe that these two provisions generally are adequate to ensure that M+C enrollees are not held responsible for fees for which an M+C organization is liable.

In instances where providers do bill M+C enrollees for amounts beyond those approved in an M+C plan, we believe that it is the responsibility of the M+C organization to take appropriate steps, such as recovering these amounts from the providers, to see that beneficiary enrollees are made financially whole. If they fail to do so, we would take appropriate action against the M+C organization. We believe it would be inappropriate for us to engage in activities directed at individual providers.

We note, however, that even in situations, (such as insolvency or other financial difficulties), where an M+C organization fails to satisfy its responsibility to pay a provider for services furnished to an M+C enrollee, the principle that the beneficiary is protected still applies. Although we believe this principle is inherent in the existing regulations, to clarify this point, we are revising §422.502(g)(1) to indicate that the applicable beneficiary financial protections apply in situations such as insolvency or other financial difficulties.

We believe that the term "fee" is commonly understood, and does not need a special definition. In this context, the term refers to the fees charged by a provider (for example, a physician's fee for services provided). M+C organizations are responsible for payment of such fees, except for applicable enrollee cost-sharing amounts specified under the M+C plan, which are the obligation of the Medicare enrollee.

Comment: A commenter contended that there is an inconsistency in the language in §§422.502(g)(2), (g)(3), and (i)(3)(i)(B). Section 422.502(g)(3) gives M+C organizations several options for meeting requirements in §422.502(g) (other than the "hold harmless" requirement in §422.502(g)(1)(i)), including the options of providing for continuation of benefits through contractual arrangements, insurance, financial reserves, or other arrangements acceptable to HCFA. Section 422.502(i)(3)(i)(B), however, effectively requires that continuation of benefits be provided for in contract language.

Response: We agree with the commenter that the language in these sections is inconsistent. Accordingly, we are revising §§422.502(i)(3)(i) to eliminate the requirement that the continuation of benefits protection be addressed through contractual arrangements. In conjunction with this technical change, we also are revising §422.502(g)(3) to clarify that the alternative arrangements spelled out there are linked only to the indemnification provision in §422.502(g)(1)(ii) and to the continuation of benefits provision in §422.502(g)(2).

7. Requirements of Other Laws and Regulations (§422.502(h))

Section 422.502(h) requires that contracts reflect the M+C organization's obligations under other laws, specifically, the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans with Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.

Comment: Several commenters wanted us to define "other laws applicable to recipients of Federal funds" and "other applicable laws and rules" as used in §422.502(h).

Response: These references are intentionally broad and all-encompassing. We have already identified various specific laws. These references are intended to encompass laws that may be enacted in the future, or current laws that we might inadvertently omit if we were to attempt to be more specific in this regulation. It is important to note, however, that these references only apply to laws that are, by definition and by their own terms, "applicable" to an M+C organization. Thus, these provisions of the regulations do not result in an organization being required to comply with any laws that do not already apply to them. Rather, they simply call for a commitment to comply with these laws.

8. Contracting/Subcontracting Issues (§422.502(i))

The requirements found at §422.502(i)(3) pertaining to M+C contracting requirements with providers, suppliers, and administrative service entities were developed pursuant to our authority under section 1856(b)(1) of the Act to "establish" M+C "standards." We developed these rules in recognition of the fact that managed care organizations commonly enter business relationships with entities that they place under contract to perform certain functions that would otherwise be the responsibility of the M+C organization. Section 422.502(i)(3) establishes these requirements in three broad categories: enrollee protection provisions, accountability provisions, and a provision that assures that services performed by other entities are carried out in a manner that complies with the M+C organization's contractual obligations to us. We received three comments concerning the subcontracting issues addressed in §422.502(i)(3).

Comment: Two commenters believe that HCFA should provide additional guidance on its contracting/subcontracting requirements; they suggested that HCFA apply a flexible standard in holding M+C organizations accountable for meeting these requirements in a timely manner. A third commenter wanted to know if our subcontracting guidance would compel entities with whom M+C organizations contract to comply with HCFA's Y2K systems compliance requirements.

Response: We are cognizant of the importance of providing detailed contracting guidance to M+C organizations, and to individuals and entities that might choose to contract with them. We have issued significant guidance in the past and intend to continue doing so as needed in the future. For example, in OPL 98.077 we addressed two major issues. First, we clarified the contracting requirements that affect M+C organizations, applicant organizations, contractors, and subcontractors. Second, we addressed implementation guidance for organizations that wished to begin operation as an M+C-contracting organization. We believe that this OPL sufficiently addresses concerns raised by the managed care industry concerning the need for a higher degree of specificity regarding contracting and subcontracting requirements. We likewise believe that OPL 98.077 established flexible implementation standards in recognition of the labor-intensive nature inherent in activities aimed at amending or otherwise establishing contracts and subcontracts that follow the standards specified in the M+C regulations and elsewhere in OPL 98.077. Commenters and other interested parties may access OPL 98.077 on the Internet at http://www.hcfa.gov.

Regarding the question on Y2K requirements, this issue is moot, since all contracting M+C organizations appear to have succeeded in avoiding related problems. We would note, however, that to the extent an M+C organization provided services through subcontractors, it was responsible for ensuring the Y2K compliance of those subcontractors to the extent necessary to ensure overall Y2K compliance.

Comment: Some commenters expressed confusion regarding use of the terms "related entities, contractors, and subcontractors" in §422.502(i)(1), and the applicability of these terms. Some have pointed out that although the term "related entity" is defined at §422.500, the terms "contractor" and "subcontractor" are not defined.

Response: In response to the confusion suggested by this comment, we now recognize that the terms "contractor" and "subcontractor" are somewhat amorphous, and could mean different things to different parties. For instance, a contract between an M+C organization and members of an IPA might be considered a "contract" by one party and a "subcontract" by another party. Likewise, organizations or individuals might sometimes call a contract between the IPA and its member physicians a "subcontract," while in other instances call it a "provider participation agreement." We have consulted with the managed care industry about terms that may be universally recognized, and have also considered developing new terminology with clear definitions.

As a result, and in response to the comment, we have added two terms--"first tier" and "downstream"--to the list of definitions at §422.500. We believe these definitions will clarify the types of entities to which the M+C contracting requirements described at §422.502(i) apply. We began using the terms "first tier" and "downstream" in OPL 98.077, and believe that both terms satisfactorily enhance the description of entities or individuals that are the intended audience for satisfying the requirements found at §422.502(i).

9. Certification of Data that Determine Payment/Certification of the Accuracy of ACR Information (§422.502(l))

Under §422.502(l), M+C organizations must certify to the accuracy, completeness, and truthfulness of the data used to calculate payments to the organizations. These data include enrollment information, encounter data, and the information included in an M+C organization's ACR proposal. In the preamble to the interim final rule, we noted that in submitting these data, M+C organizations are making a "claim" for payment from HCFA, since this information directly affects the calculation of payment rates and amounts. We stated that the certifications would help ensure accurate data submissions and assist us in maintaining the integrity of the Medicare program.

Comment: Several commenters suggested that the certification requirement should include a "good faith" standard.

Given the significance of the penalties that HCFA, OIG, and the Department of Justice (DoJ) may potentially impose in the case of a "false claim," and the complexity of the data required, these commenters believe that it would be unfair and unrealistic to hold M+C organizations to a "100 percent accuracy" certification standard.

Response: We first addressed this issue during the drafting of the 1999 M+C coordinated care plan contract. In developing the certification forms M+C organizations would use to meet the payment data certification requirement, we consulted with OIG and DoJ in drafting language that requires the M+C organization to certify the accuracy, completeness, and truthfulness of this data based on "best knowledge, information, and belief." This language was included in the 1999 contract forms in recognition of the fact that M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce.

In presentations to industry, HHS representatives have emphasized that simple mistakes will not result in sanctions. Generally, the Federal government can bring an action only when one of three states of mind exists: 1) actual knowledge of falsity of a claim or information; 2) reckless disregard; or 3) deliberate ignorance of information supporting the truth or falsity of a claim or other information (42 CFR 1003.101). However, no specific intent to defraud is required. The "best knowledge, information, and belief" standard of the M+C contract certification forms is consistent with these standards.

It is appropriate that the M+C regulations be consistent with the standard of knowledge reflected in Federal fraud statutes. Therefore, we are modifying §422.502(l) as needed to reflect the "best knowledge, information, and belief" certification standard.

Comment: Several commenters suggested that the signatory authority for payment certifications should not be limited to the chief executive officer (CEO) and chief financial officer (CFO) of an M+C organization. The commenters noted that as a practical matter, it is difficult to obtain a CEO or CFO signature on a monthly basis, given the workload and travel obligations of these officers. Therefore, the regulations should permit a CEO or CFO to designate another individual in the M+C organization to sign the certifications.

Response: We agree that the CEO/CFO signature requirement can create operational difficulties for M+C organizations in their efforts to comply with the payment certification requirements of §422.502(l). However, we believe that it is important that certifications be made by a high level individual who has authority to obligate the M+C organization, or someone who has been delegated the authority of such an individual. Therefore, we are modifying §422.502(l) to require the "CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such an officer," to certify the M+C organization's enrollment data, encounter data, and ACR proposal information.

Comment: A commenter contended that M+C organizations should not be required to certify the accuracy of the encounter data they receive from third parties. Rather, this commenter believes that organizations should be required to certify only that they have not altered the data, and that they have transmitted it to HCFA as they received it from the provider. The commenter asserted that M+C organizations do not control the operations of those providing encounter data, and that the volume of data is such that no M+C organization has the resources to verify the accuracy of these submissions.

Response: Under the M+C program, encounter data will be used as a factor in calculating payments to M+C organizations. Therefore, encounter data submissions, like enrollment data and ACR information, represent a "claim" for payment. As such, M+C organizations have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data.

We acknowledge that encounter data come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake "due diligence" to ensure the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a "best knowledge, information, and belief " standard. Therefore, M+C organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.

10. Effective Date and Term of Contract (§422.504)

Section 1857(c)(3) of the Act provides that the effective date of an M+C contract is to be specified in the M+C contract, and section 1857(c)(1) requires that contracts be for a term of at least one year. The Secretary was provided the discretion under section 1857(c)(1) to provide for contracts to be "automatically" renewable in the absence of notice.

Section 1857(c)(2) of the Act authorizes us to terminate an M+C contract if we determine that an M+C organization substantially fails to carry out its M+C contract, carries out the contract in a manner that is inconsistent with the effective and efficient administration of the M+C program, or fails to continue to meet the M+C requirements.

Section 422.504 of the June 1998 interim final rule implements section 1857(c)(1) and (3) of the Act. Section

422.504(b) provides that contracts generally are for a 12-month period beginning January 1 and ending December 31. Section 422.504(d) provides for a limited exception to this rule, permitting HCFA the discretion, prior to January 1, 2002, to approve a contract for longer than 12 months beginning on a date other than January 1. This decision permits us to accept M+C applications on a continuous "flow" basis until the beginning of the lock-in periods contemplated under the BBA starting in 2002. We received one comment pertaining to the effective date and term of the M+C contract.

Comment: A commenter expressed concerns regarding the effect of open enrollment requirements on our requirements governing the effective date and term of M+C contracts. In particular, the commenter had concerns about the elimination of the right to disenroll (and enroll) in an M+C plan at any time. The commenter believes that this shift in enrollment policy contributed to our decision no longer to approve contract applications on a continuous "flow" basis after 2002, since most Medicare beneficiaries, (excluding newly eligible beneficiaries and those beneficiaries eligible to make an election based upon a special enrollment period), would not otherwise be able to enroll in the new M+C organization until the beginning of the next annual open enrollment period. The commenter suggested that M+C organizations retain the ability to enroll Medicare beneficiaries on an ongoing basis without regard to the annual lock-in periods contemplated by the BBA at section 1851(e).

Response: This comment raises two related issues. The first pertains to enrollment and disenrollment policies, and the second pertains to HCFA's rationale for considering a policy that would establish a cutoff date for making contracts effective on a date other than January 1. We believe the statute clearly indicates that continuous open enrollment and disenrollment may continue only through the end of 2001. Currently, M+C organizations are only required to be open for enrollment in November of each year, to newly Medicare-eligible individuals, and during specified "special election periods." (See §422.60(a).) Thus, it is not necessarily the case even now that there is "continuous" open enrollment, though the right to disenroll exists all year. During the first 6 months of the transition year of 2000, a beneficiary will be able to disenroll without cause, and enroll in any M+C plan open for enrollment, with a limit of one change in enrollment status during this period. This same situation will apply to the first 3 months of every year after 2002, with a limit of one change in elections during this 3-month period. Other than this, beneficiaries will only be permitted to enroll or disenroll during the annual November open enrollment period, a special election period, or upon first becoming eligible for Medicare (with the exception of institutionalized individuals, consistent with section 501 of the BBRA). These enrollment limitations will, in effect, limit the number of Medicare beneficiaries that an M+C organization can enroll mid-year. Yet, after considering the comments, we do not believe that the enrollment policies pursuant to the BBA necessarily preclude us from entering into contracts on dates other than January 1 beginning 2002. While we recognize the inherent enrollment limitations for M+C organizations that will result from a mid-year enrollment eligibility pool that will be comprised largely of individuals that become newly eligible for Medicare, we nevertheless believe that enrollment and the term of an M+C contract are distinct issues that can be considered independent of each other. Regarding the term of an M+C contract, we further believe that the statute permits us to continue to approve mid-year contracts post-2002. Since section 1857(c)(1) requires that contracts be for a term of at least one year, HCFA may continue to enter contracts that may begin on dates other than January 1 for terms longer than 12 months. We have modified §422.504 to reflect this policy.

11. Nonrenewal of M+C Contracts (§422.506)

Section 422.506 specifies the process that M+C organizations and HCFA must use should HCFA decide not to renew the organization’s contract, or should the organization give HCFA notice that it does not want its contract to be renewed. We received four comments addressing our M+C contract renewal policy.

Comment: Some commenters believe that requiring M+C organizations to notify HCFA of their intent to nonrenew their M+C contract(s) by May 1 does not provide enough time for organizations to conduct the requisite analysis necessary to decide whether the organization should remain in the M+C program.

Response: We agree with the commenter that the May 1 deadline does not provide organizations enough time to decide whether to remain in the M+C program. We recognize that the May 1 deadline affords organizations only 60 days from the date such organizations received the upcoming year's M+C payment rates to make business decisions affecting their participation in the M+C program. Congress recently recognized this problem when it amended section 1854(a)(1) of the Act to change the deadline for submitting an ACR from May 1 to July 1. (See section 516 of the BBRA and section I.C of this preamble.) In light of the commenter’s concern, and the change in the ACR deadline enacted by Congress, we are revising §422.506(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year. An M+C organization that does not signify its intent not to renew its M+C contract by July 1, and that has not otherwise been notified by HCFA of our intent not to renew the M+C organization's contract by May 1, will be obligated to contract for the upcoming contract year.

Comment: One commenter questioned our authority under §422.506(b)(ii) to decide not to renew M+C contracts based on our assessment that an M+C organization's level of enrollment or growth in enrollment threatens the viability of the organization under the M+C program. This commenter likewise questioned the authority under which we could decide not to renew a contract based upon our assessment that lack of enrollment could be viewed as an implied measure of dissatisfaction with a particular M+C organization.

Response: We believe that HCFA should be a prudent purchaser of health care services on behalf of Medicare beneficiaries. This entails a fiduciary responsibility to Medicare beneficiaries and tax payers to maintain contracts with organizations that display a sustained and ongoing commitment toward meeting the highest quality standards, and that offer a product attractive enough to attract Medicare beneficiaries to enroll. In promulgating §422.506(b)(1)(ii), we determined that it might not be worth the costs associated with contracting with an M+C organization if that organization fails to attract or keep at least some level of Medicare enrollment.

However, in response to the commenter’s concern, we have determined that the standard outlined at §422.506(b)(1)(ii) for declining to renew an M+C contract may be too vague to enforce; therefore, we are deleting §422.506(b)(1)(ii).

12. Provider Prior Notification and Disclosure (§§ 422.506(a), 422.508, 422.510(b), and 422.512)

We address M+C contract determinations in several sections throughout subparts K and N of the M+C regulations. As noted above, §422.506 contains provisions governing our decisions and M+C organization decisions concerning whether to renew an M+C contract. Section 422.508 specifies that HCFA and an M+C organization may together elect, upon mutual consent, to modify an M+C contract. Sections 422.510 and 422.512 describe M+C contract termination procedures when initiated by either HCFA or an M+C organization. When M+C contract determinations occur, either the organization initiating the determination, or the organization impacted by the determination, must meet certain notification requirements described in §§422.506, 422.508, 422.510, and 422.512. The notice requirements compel either HCFA or the M+C organization to notify: (1) the party affected by the contract determination (for example, if HCFA elects to terminate a contract, HCFA must notify the M+C organization of our determination); (2) the Medicare beneficiaries from the affected M+C organization's M+C plans; and (3) the general public.

Comment: Several commenters suggested that we consider developing a requirement that would compel HCFA and/or an M+C organization to notify providers affected by M+C contract determinations about the contract determination, regardless of which party initiates the contract determination action. The commenters contended that the notice is necessary to grant providers sufficient time to react to contract determinations that may adversely affect them. (A related section of regulations that the commenters did not reference, but would logically be affected by the recommendations of the commenters, is §422.641 of subpart N.)

Response: We believe there are several reasons why separate provider disclosure and notification is unnecessary. First, we do not believe that notifying an M+C organization's network providers of an M+C contract determination is feasible for HCFA, since we do not routinely maintain this information at a level of specificity that would be necessary to provide such notice. Further, we do not believe that it is necessary to require M+C organizations to provide such notice, since we believe that they would necessarily have to notify affected providers that their contracts were being nonrenewed.

In any event, since M+C organizations and/or HCFA are already required to disclose specified information to the general public, a subset of which are the M+C organization's providers, pursuant to an M+C contract determination, we believe that any additional notification requirements may be duplicative and unnecessary.

13. Mutual Termination of a Contract (§422.508)

Section 422.508 provides that M+C organizations and HCFA may mutually agree to modify or terminate an M+C contract. When a contract is terminated by mutual consent, M+C organizations must provide notice to affected Medicare enrollees and the general public. If the contract terminated by mutual consent is replaced on the following day by a new M+C contract, the notice requirements do not apply.

Comment: One commenter expressed concerns that our policy, as outlined at §422.508, does not provide enough beneficiary protection, and may potentially compromise beneficiary continuity of care. Further, the commenter recommended that mutual contract termination should automatically trigger a special enrollment period for affected Medicare beneficiaries, as outlined at §422.62(b).

Response: We believe that §422.508 provides Medicare beneficiaries affected by mutual consent contract termination with the protections necessary for affected beneficiaries to choose new Medicare health service delivery options. In particular, the requirement that M+C organizations provide Medicare beneficiaries and the general public with a notice of termination to conform to the 60-day notice requirement in

§§422.512(b)(2) and (3) should enable affected Medicare beneficiaries to arrange for alternative health care coverage, such as returning to original Medicare, or choosing a different M+C plan before the effective date of termination.

We agree with the commenter that a termination (and not modification) of an M+C contract by mutual consent should trigger a special election period as described at §422.62(b), and we believe that the existing language at §422.62(b)(1) supports this position. In stating "HCFA has terminated.....or the organization has terminated.....the [M+C] plan in the service area or continuation area in which the [Medicare eligible] individual resides....," we believe that termination of a contract by mutual consent of the two aforementioned parties is consistent with the intent of the provision at §422.62(b)(1). Thus, we believe that any change to the regulation language at §422.508 or §422.62(b)(1) is unnecessary.

14. Termination of Contract by HCFA (§422.510)

Section 422.510 implements the provisions in section 1857(c)(2) of the Act pertaining to our authority to terminate an M+C organization's contract if we determine that the organization: (1) fails to substantially carry out the contract; (2) is carrying out the contract in a manner inconsistent with the efficient and effective administration of Medicare Part C; and/or (3) no longer substantially meets the applicable conditions of Part C. In §422.510(a), we set forth the above standards, as well as several specific circumstances that we believe constitute a substantial failure to carry out the contract, justifying termination. The procedures under which we would take action to terminate an M+C contract are described in section 1857(h) of the Act. In general, we may terminate an M+C contract after: (1) we provide the M+C organization with an opportunity to correct identified deficiencies; and (2) we provide the organization with notice and opportunity for a hearing, including the right to an appeal of an initial decision.

We received three comments on §422.510. One commenter requested further explanation regarding the termination process, for which we refer the commenter to subpart N of the regulations. The other comments are addressed below.

Comment: Two commenters requested that we define what we mean by the term "substantially fails to comply," as used throughout §422.510(a).

Response: In the June 1998 interim final rule, and at §422.510(a)(4) through (11), we identify circumstances that we believe constitute examples of what the statute identifies as substantially failing to carry out an M+C contract. They are: the M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program; the M+C organization substantially fails to comply with requirements in subpart M relating to grievances and appeals; the M+C organization fails to provide us with valid encounter data as required under §422.257; the M+C organization fails to implement an acceptable quality assessment and performance improvement program as required under subpart D; the M+C organization substantially fails to comply with the prompt payment requirements in §422.520; the M+C organization substantially fails to comply with the service access requirements in §§422.112 or 422.114; or the M+C organization fails to comply with the requirements of §422.208 regarding physician incentive plans.

We have longstanding compliance standards for Medicare managed care contractors. In addition to those set forth in the statute and regulations, compliance standards are set forth in our Medicare Managed Care Performance and Monitoring protocol. We use this document when conducting performance/monitoring evaluations of contracting Medicare managed care organizations, including M+C organizations. Pursuant to these reviews, each contracting organization must demonstrate that it again complies with all applicable statutory, regulatory and contract requirements that apply to M+C organizations. These reviews result in findings as to whether a failure to comply with requirements constitutes a "substantial failure" for purposes of §422.510(a). In determining whether a failure is "substantial," we consider both the frequency and the seriousness of the noncompliance. In the case of a serious violation that could put the health of an enrollee at risk, even a single violation might be considered substantial. In the case of a less serious violation, the noncompliance would have to be more pervasive or systematic in order to be considered substantial.

Comment: Some comments reflected confusion regarding §422.510(c), and its reference to subpart N of part 422. Section 422.510(c) indicates that if we make a determination to terminate an M+C contract, we must first allow the affected M+C organization the opportunity to submit a corrective action plan in accordance with "time frames specified at subpart N" of part 422. The commenter noted that subpart N does not contain any time frames that apply specifically to activities related to corrective actions.

Response: We agree that subpart N does not contain time frames that appear applicable to an opportunity to take corrective action, and that this reference is an error. We accordingly are deleting this reference from §422.510(c).

15. Minimum Enrollment Requirements (§422.514)

Section 1857(b) of the Act specifies that we may not enter into a contract with an M+C organization unless the organization has at least 5,000 enrollees (or 1,500 if it is a PSO), or at least 1,500 enrollees (or 500 if it is a PSO) if the organization primarily serves individuals residing outside of urbanized areas.

Section 1857(b)(3) creates a transition standard for meeting this requirement by allowing us to waive the minimum enrollment requirement during the M+C organization’s first 3 years.

Comment: A commenter asked if we would consider a permanent minimum enrollment waiver for "smaller scale service models."

Response: A review of both the statute at section 1857(b) of the Act and the Conference Committee report indicates that the Congress intended for the minimum enrollment waiver to apply only during the first 3 contract years for any organizations. The minimum enrollment thresholds themselves are necessary to enable organizations to adequately spread risk across enrolled populations.

16. Reporting requirements (§422.516)

The M+C regulations contain various provisions that specify information disclosure requirements. The requirements address both information to be provided by M+C organizations to HCFA (see §§422.64, 422.502, and 422.512), by M+C organizations to beneficiaries (see §§422.80 and 422.111), and by HCFA to beneficiaries (under existing §422.64). Section 422.516 specifies requirements that M+C organizations must meet regarding disclosure of statistics and information to HCFA, M+C enrollees, and the general public.

Comment: A commenter requested that we expand the reporting requirements specified at section §422.516 to require M+C organizations to report the statistics and other information specified in §422.516 et seq. directly to the organization's network health care providers.

Response: The commenter seeks to carve-out a separate category of individuals, providers, to receive statistics and other information that M+C organizations are already obligated to disclose to HCFA, to M+C plan enrollees, and to the general public. We believe that it is unnecessary for M+C organizations to report statistics and other information separately to providers. Since M+C organizations (or HCFA) are already required to disclose specified information to the general public, (a subset of which is the M+C providers), any additional requirement to disclose information separately to an organization's providers is duplicative and unnecessary. Moreover, we are concerned about the administrative burden that such a requirement could impose upon M+C organizations, which may contract with thousands of providers. Further, we suspect that many organizations already voluntarily furnish providers with much of the information required under §422.516, such as information on health plan benefits, premiums, quality and performance measurements, and utilization control mechanisms.

17. Prompt Payment by M+C Organization (§422.520(a))

Section 422.520 indicates that contracts between M+C organizations and HCFA must specify that the M+C organization agrees to provide prompt payment of claims that have been submitted by providers for services and supplies furnished to Medicare enrollees when these services and supplies are not furnished by an organization-contracted provider. Specifically, 95 percent of "clean claims" must be paid within 30 days of receipt. While this provision closely follows requirements already in place for section 1876 contractors, (including provisions pertaining to interest to be paid if timely payment is not made), section 1857(f) of the Act extends similar prompt payment requirements to claims submitted by Medicare beneficiaries enrolled in M+C private fee-for-service plans. Section 422.520(a) incorporates this requirement of new section 1857(f), as well as the general 30-day requirement that applied to noncontracting providers under section 1876. In the preamble to the June 1998 interim final rule, we indicated that pursuant to our authority under section 1856(b)(1) to establish standards under Part C, M+C organizations would be required to act upon (either approve or deny, not necessarily pay) all claims not subject to the 30-day standard within 60 calendar days from the date of request.

Comment: Commenters noted that the "approve or deny" language in §422.520(a)(3) was inconsistent with rules regarding M+C organization determinations and reconsiderations as described in subpart M. Also, it has been brought to our attention that the requirement that "non-clean" claims (and up to 5 percent of clean claims) be "approved or denied," but not necessarily paid, within 60 calendar days from the date of the request for payment, is inconsistent with the standard that applied to contractors under section 1876 of the Act. Under the Medicare risk program, HCFA traditionally required that HMOs or CMPs with Medicare risk contracts pay or deny non-clean claims within 60 calendar days from the date of the request for payment. The "approve or deny" language may permit gaps of time between when an organization approved a claim for payment and when the organization actually paid a claim.

Response: After further review of this issue, we agree that M+C organizations should be required to either pay or deny non-clean claims (and clean claims not subject to the 30-day standard) within 60 calendar days from the date of the payment request. This standard removes the possible ambiguity associated with "approving", but not necessarily paying, a claim for payment, and any related ambiguities pertaining to M+C organization determination and reconsideration policies articulated in subpart M of this final rule. Thus, we are revising §422.520(a)(3) to indicate that claims for services that are not furnished under a written agreement between M+C organization and its network providers, and that are not paid within 30 days, must be either paid or denied within 60 calendar days from the date of the request.

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract (Subpart L)

The provisions set forth in subpart L of part 422 by the June 1998 interim final rule merely constituted a redesignation of the provisions in part 417 on change of ownership or leasing of facilities. However, since the June 1998 interim final rule was published, it has come to our attention that M+C organizations have serious concerns about language in the italicized title to §422.550(a)(2) which has been construed to present an impediment to an asset sale by one corporation to another. Section 422.550(a) sets forth what constitutes a "change of ownership" for purposes of provisions in §422.552 which permit an M+C contract to be transferred to a new owner under certain circumstances (for example, the new owner must meet the requirements to qualify as an M+C organization). Because this italicized title refers to an "unincorporated sole proprietor," it suggests that a "[t]ransfer of title and property to another party" does not constitute a change of ownership if the assets are transferred by a corporation, rather than a sole proprietor. This has presented problems in cases in which transactions that would benefit Medicare beneficiaries by keeping a M+C plan option available do not appear to fall within the definition of change of ownership. If an M+C contract accordingly could not be transferred as part of an asset sale, this could prevent the sale from going forward, or limit the sale to commercial or Medicaid lines of business, in either case, potentially depriving Medicare beneficiaries of an M+C plan option they would otherwise have.

The italicized language in question was adopted from rules in section 1876 of the Act, which in turn were adopted from longstanding original fee-for-service Medicare change of ownership regulations containing identical language (see §489.18(a)). These original Medicare change of ownership regulations apply to a change of ownership in the case of a Medicare provider, and address the assumption of a Medicare provider agreement, rather than an M+C contract. However, the language in §489.18(a)(2) is identical to that in §422.550(a)(2). In the original Medicare context, this language has consistently been interpreted to encompass an asset sale from one corporation to another. This interpretation was applied by the U.S. Court of Appeals for the Fifth Circuit in U.S. v. Vernon Home Health Care Inc., 21 F.3d 693 (5th Cir.), cert. denied, 115 S. Ct. 575 (1994). While we have determined that the current M+C change of ownership regulation containing identical language should similarly be interpreted to encompass an asset sale by a corporation, we believe that it would be helpful to eliminate the reference in the title of §422.550(a)(2) to a "sole proprietorship" in order to avoid confusion. We therefore are changing this title in this final rule to read "Asset sale."